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VIA E-MAIL (Jim.Christoffersen@tn.gov)

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Tennessee Health Facilities Commission
502 Deaderick Street, 9th Floor
Nashville, TN 37243

Re: TriStar Hendersonville Medical Center – Certificate of Need Application -
Gallatin FSED – CN2305-012

Dear Jim:

This letter comes on behalf of my client TriStar Hendersonville Medical Center (“TriStar Hendersonville”) to address certain points in the Staff Report in CN2305-012 released on July 14, 2023 (“the Staff Report”), wherein the Staff found that TriStar Hendersonville did not meet or only partially met certain Standards and Criteria.

TriStar Hendersonville requests that the Staff revisit certain conclusions in the Staff Report discussed in depth below and summarized as follows:

- (1) The provision in Criteria #1 that “[a]ll existing EDs in the service area should be operating at capacity” is an improper consideration given that **“orderly development” was removed from the CON law in 2021.**
- (2) In Criteria #1, the Staff read “all EDs in the service area” to be **“a requirement”** while both Criteria #1 and the statute itself provide that the levels are to be **“a guideline.”** Standards & Criteria, p. 3 (emphasis added); Tenn. Code Ann. § 68-11-1609(b).
- (3) As to Criteria #1, the Staff’s reading of the importance of the “all ERs in the service area” provision is inconsistent with the language in the very next sentence in Criteria #1 itself, which says that the “determination should be based

upon the annual visits per treatment room at the host hospital's emergency department.” Standards & Criteria, p. 3 (emphasis added).

- (4) As to Criteria #1, the Staff ignored that **Criteria #1 points to Criteria #2 for use in Capacity Challenges** based projects like this one. Standards & Criteria, p. 5.
- (5) As to Criteria #1, the countywide data shows that **Sumner County is facing Capacity Challenges** and that those challenges continued into 2022. *See* pp. 9-10, *infra*.
- (6) As to Criteria #1, the Staff relied on Applicant's good wait times to find that the Criterion was not met despite Criteria #1's own statement that “Host hospitals applying to establish a FSED displaying efficiencies in care delivery via high volumes **and low wait time should not be penalized** in the review of this standard.” Standards and Criteria, pp. 5-6 (emphasis added). Further, as to wait times, **no other post-2021 CON Reform FSED CON Application has been found by the Staff to not meet Criteria #1 based on good wait times**. And it is materially inconsistent for Criteria #1 to require an applicant to have bad wait times while at the same time good wait times are required to meet Criteria #4.
- (7) As to Criteria #1, the Staff attributes excessive importance to the fact that Applicant has good Left Without Being Seen performance given the “**should not be penalized**” language in the Criteria #1 about wait times noted above.
- (8) Criteria #3 also considers the **impact on existing providers, which was eliminated by the 2021 CON Reform law** and special circumstances do exist: the Staff recognized population growth as a special circumstance and in this matter the fact that consumers prefer TriStar Hendersonville as their emergency care provider is an additional important special circumstance.

I. Background

In 2017, the Governor approved the 2016 State Health Plan that incorporated specific Standards and Criteria to be used as guidance in the evaluation of CON applications for the establishment of Freestanding Emergency Departments (FSEDs).¹ While the Tennessee Health Services and Planning Act of 2021 adopted substantial changes in Certificate of Need (CON) law, Tenn. Code Ann. § 68-11-1601 *et seq*, the FSED Standards & Criteria are the same as they were in 2017.

¹ <https://www.tn.gov/health/health-program-areas/health-planning/health-planning-announcements.html>

The primary structural change in CON law in 2021 was the removal of “orderly development” and “economic feasibility” from the statutory requirements for the evaluation of CONs and the addition of “the effects attributed to competition or duplication would be positive for consumers” (“consumer advantage”). Tenn. Code Ann. § 68-11-1609(b) (2021). This is demonstrated by the following slide from the CON Reform Presentation shown at the June 23, 2021 agency meeting, which appears on the HFC’s website:

Changes to Standards and Criteria under PC 557

1. Need
 - a) Population to be served
 - b) Minimum utilization levels
2. Economic Feasibility
 - a) Adequacy of funds to complete the project
 - b) Sustainable revenue projections
3. Contribution to the Orderly Development of Health Care -> Consumer Advantage
 - a) Impact on existing patients
 - b) Impact on existing providers
4. Appropriate Quality Standards
 - a) Accreditation by respected organization

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Previously, orderly development was used in part to determine “whether the proposed project will have **negative effects or impact on other existing providers.**” *In re TriStar Southern Hills Medical Center Emergency Department at I-65*, No. 25.00-130740J, at 44 (Initial Order, May 31, 2017) (emphasis added).³ Therefore, as a matter of law, **considering the impact on other providers is no longer supported by the CON statute.** As a result, the HFC’s Rule articulating the General Criteria for the evaluation of CONs does not include “orderly development.” *See* 0720-11-.01 General Criteria for Certificate of Need.

Fundamentally, **neither regulations nor guidance material can extend legal authority beyond the substantive grant of authority contained in the legislation establishing the governing law.** *Tasco Developing & Bldg. Corp. v. Long*, 212 Tenn. 96, 102, 368 S.W.2d 65, 67 (1963) (“an administrative body . . . does not have the power to

² CON Reform Working Group Presentation (tn.gov) (striking out “~~Contribution to the Orderly Development of Health Care,~~” and “~~Impact on existing providers~~” to demonstrate removal of these issues from the Tennessee Health Services and Planning Act of 2021) (yellow highlight emphasis added).

³ On October 25, 2017, the HSDA declined to review this Initial Order.

make a rule or regulation which is inconsistent with the . . . law on the subject”). “Any action by the [Commission] must be based on an express statutory grant of authority or must arise by necessary implication from an express statutory grant of authority.” *Hammond v. Harvey*, 410 S.W.3d 306, 309 (Tenn. 2013) (citing *Sanifill of Tenn., Inc. v. Tenn. Solid Waste Disposal Control Bd.*, 907 S.W.2d 807, 810 (Tenn. 1995)). “An action by an administrative agency that exceeds the scope of authority delegated to the agency by the legislature has no force or effect.” *Id.* (citing *Faust v. Metro. Gov’t of Nashville*, 206 S.W.3d 475, 498 (Tenn. Ct. App. 2006)).

Because the statutory grant of authority for considering the impact on existing providers has been removed from the CON statute, any Criteria that includes considering such impact -- such as “[a]ll EDs in the service area should be operating at capacity” in Criteria #1 and “the likely impact of the proposed FSED on existing EDs in the service area” in Criteria #3 -- **are no longer legitimate guidance for the Commission**. Therefore, the Staff should revise the Staff Report because the criteria that the Staff found TriStar Hendersonville did not meet are “orderly development” criteria, which after the 2021 amendment to the CON law no longer have any legal foundation.

II. Staff Report - TriStar Hendersonville FSED CON Application

A. Criteria #1 - Introduction

Criteria #1 provides that an applicant, such as TriStar Hendersonville in this case, can show Need based on geographic isolation, capacity challenges, or low-quality of care.

Determination of Need: The determination of need shall be based upon the existing access to emergency services in the proposed service area. The applicant should utilize the metrics below, as well as other relevant metrics, to demonstrate that the population in the proposed service area has inadequate access to emergency services due to geographic isolation, **capacity challenges**, or low-quality of care.

Standards and Criteria, p. 3 (emphasis added). Criteria #1 goes on to explain how to evaluate Need, however, ***without distinguishing between which of the three types of Need showing*** the applicant is making:

The applicant shall provide information on the number of existing emergency department (ED) facilities in the service area, as well as the distance of the proposed FSED from these existing facilities. If the proposed service area is comprised of contiguous ZIP Codes, the applicant shall provide this information on all ED facilities located in the county or counties in which the service area ZIP Codes are located.

The applicant should utilize Centers for Medicare and Medicaid Services (CMS) throughput measures, available from the CMS Hospital Compare website, to illustrate the wait times at existing emergency facilities in the proposed service area. Data provided on the CMS Hospital Compare website does have a three to six month lag.

In order to account for the delay in this information, the applicant may supplement CMS data with other more timely data.

The applicant should also provide data on the number of visits per treatment room per year for each of the existing emergency department facilities in the service area. Applicants should utilize applicable data in the Hospital Joint Annual Report to demonstrate the total annual ED volume and annual emergency room visits of the existing facilities within the proposed service area. **All existing EDs in the service area should be operating at capacity. This determination should be based upon the annual visits per treatment room at the host hospital's emergency department (ED) as identified by the American College of Emergency Physicians (ACEP) in *Emergency Department Design: A Practical Guide to Planning for the Future, Second Edition* as capacity for EDs. The capacity levels set forth by this document should be utilized as a *guideline* for describing the potential of a respective functional program.** The annual visits per treatment room should exceed what is outlined in the ACEP document. Because the capacity levels set forth in the *Emergency Department Design: A Practical Guide to Planning for the Future, Second Edition* are labeled in the document as a "preliminary sizing chart", the applicant is encouraged to provide additional evidence of the capacity, efficiencies, and demographics of patients served within the existing ED facility in order to better demonstrate the need for expansion.

Standards & Criteria, p. 3 (emphasis added).

The foregoing includes "orderly development" considerations – which are no longer legally supportable. Further, the three bolded sentences should be read together, and none should be given the status level of "a requirement."

1. "All EDs"

Regarding Criteria # 1, the Staff found that because 1 of the 4 emergency departments in Sumner County was not operating at or above the ACEP level, TriStar Hendersonville did not meet Criteria #1.

While three of the four Sumner County emergency departments exceed ACEP recommended ranges, Sumner Regional Medical Center falls below the ACEP recommended ranges and is located within the same ZIP Code 37066 (Gallatin) as both the proposed TriStar Gallatin FSED and the existing Sumner Station FSED.

Therefore, it does not appear that this portion of Criterion - Capacity Challenges (Visits per Treatment Room) is met by the applicant as the Criterion requires that "All existing EDs in the service area should be operating at capacity. I]"

Staff Report, p. 5 (underline emphasis provided by Staff).

a. The "All EDs" provision is not legitimate under current CON law

The Staff labeled this "All EDs" portion of Criteria #1 as a "requirement." The "All EDs" sentence is not a legitimate requirement because measuring whether all EDs

are at capacity is really an orderly development concern, which is no longer relevant to CON law.

Criteria #1 recognizes “capacity challenges” as basis for granting a CON. Most of the language in Criteria #1 that obviously relates to capacity challenges is directed to capacity challenges at the host hospital. If “capacity challenges” is intended to address capacity issues in the service area (which TriStar Hendersonville submits it is not), then as noted on pages 9 and 10, the service area and Sumner County generally are above the ACEP capacity levels.

As read by the Staff as requiring that all individual ERs are at capacity, this is an orderly development concern because it is focused on the impact on providers other than the host hospital. That concern -- impact on other providers -- was removed from CON jurisprudence with the amendment of the CON statute in 2021. Accordingly, whether other EDs in the service area are at capacity is irrelevant for establishing whether the host hospital is at capacity or whether the overall ED system in the service area or county is at capacity.

The “All EDs” provision if used by the HFC in every case would make the Capacity Challenges basis for a CON meaningless. Reading Criteria #1 as requiring “All EDs” to be at capacity makes the Capacity Challenges need consideration always subject to the ability of other ERs in the service area to attract patients, basically stranding successful Emergency Rooms to remain crowded and at/over capacity while other EDs languish. That is not a legitimate basis for denying access to emergency care, unless some “orderly development” consideration is the reason.

Moreover, it is legally unsupportable to say that one must demonstrate need by showing all EDs in a service area are at capacity under the 2021 statute that removed “orderly development” from the statutory requirements. **The 2021 statute removed orderly development from the law so requiring all EDs to be at capacity is not a legitimate ‘requirement’ under the governing law.**

b. Use as a Guideline

The Staff cannot make the “All EDs” sentence into a requirement because Criteria #1 says the ACEP levels are to be used as “a guideline” and because the CON Statute makes the Criteria themselves merely “guidelines.” *See* Tenn. Code Ann. § 68-11-1609(b).

The importance of the Staff’s finding with respect to the “All EDs” provision and the Staff’s labeling of it as a requirement was brought into clear focus by the decision by the Commission on July 26, 2023, to deny the Tennova Knoxville CON Application

CN2304-011, wherein the motion to deny specifically quoted this alleged “All EDs” requirement.⁴

The Staff’s labeling of the capacity levels at “All EDs” as a “requirement” conflicts language in Criteria #1 and statute itself. Criteria #1 – when referring to the ACEP capacity levels that the Staff says is a “requirement” – specifically says: “The capacity levels set forth by this document **should be utilized as a guideline** for describing the potential of a respective functional program.” Standards and Criteria, p. 3 (emphasis added).

The statute itself provides that the criteria are to be used as guidelines.

[T]he commission shall use as guidelines the goals, objectives, *criteria*, and standards adopted to guide the commission in issuing certificates of need. Until the commission adopts its own criteria and standards by rule, those in the state health plan apply.

Tenn. Code Ann. § 68-11-1609(b) (emphasis added). Respectfully, the Staff does not have the authority to make what the statute says are guidelines into a “requirement.”

The “All EDs” requirement language of the Staff Report in CN2304-011 was used by the Commission to defeat the Tennova Knoxville application. The motion to deny quoted that very part of the Tennova Knoxville Staff Report. **This shows the importance of the Staff articulating properly that the “All EDs” sentence is not a “requirement.” The statute itself says that the Criteria are only “guidelines.”**

⁴ In the Tennova Knoxville matter, 4 of the 6 Knox County EDs were not operating at capacity:

2021 Service Area Emergency Department Utilization and ACEP Ranges					
Emergency Department	Total Visits 2021	# of Rooms 2021	# Visits per Room	ACEP Low Range	ACEP High Range
Exceeded ACEP Range					
Tennova North Knoxville Medical Center	38,186	20	1,909	1,522	1,250
Tennova Turkey Creek Medical Center	20,932	12	1,744	1,429	1,250
Below ACEP Range					
Parkwest Medical Center	37,589	39	964	1,522	1,250
Fort Sanders Regional Medical Center	41,553	46	903	1,600	1,212
East Tennessee Children’s Hospital	41,723	36	1,159	1,600	1,212
University of Tennessee Medical Center	85,109	78	1,091	1,604	1,250

Source: CN2304-011, Attachment 1N, Page 4
Joint Annual Report for Hospitals 2021

This compares to only 1 of 4 EDs in Sumner County operating below ACEP level:

2021 Sumner County Emergency Department Utilization and ACEP Ranges					
Emergency Department	Total Visits 2021	# of Rooms 2021	# Visits per Room	ACEP Low Range	ACEP High Range
Exceeded ACEP Range					
TriStar Hendersonville Medical Center	35,519	20	1,776	1,522	1,250
TriStar Portland FSED	11,319	8	1,415	1,250	909
Sumner Station FSED	10,649	8	1,331	1,250	909
Below ACEP Range					
Sumner Regional Medical Center	28,774	26	1,107	1,429	1,200

Source: CN2305-012, Attachment 1N, Page 16R
Joint Annual Report for Hospitals 2021

c. Criteria #1 says the determination of Need should be made based on annual visits per treatment room at the host hospital

The “All EDs” provision quoted by the Staff does not stand alone or in isolation in Criteria #1. The *very next sentence* states:

This determination should be made based upon the annual visits per treatment room at the host hospital’s emergency department (ED).

Standards and Criteria, p. 3 (emphasis added).

These two sentences are irreconcilable with each other. It is inconsistent for Criteria #1 to require that “All EDs” be at capacity and to say that one shows how “All EDs” are at capacity by showing that the host hospital’s annual visits per treatment room demonstrate that it is at capacity.

Considering the sentence in Criteria #1 that the Determination of Need is to be based on “the annual visits per treatment room at the host hospital’s ED,” then capacity levels at other EDs are not even part of the Need analysis. This is further supported by the removal of the consideration of impact on other providers from the CON statute as noted earlier.

d. Criteria #1 refers to Criteria #2 for evaluating Capacity Challenges

Criteria #1 itself points to Criteria #2 in a Capacity Challenges case such as this.

See Standard 2, Expansion of Existing Emergency Department Facility, for more information on the establishment of a FSED for the purposes of decompressing volumes and reducing wait times at the host hospital’s existing ED.

Standards and Criteria, p. 5. If the “All EDs” sentence relied upon by the Staff governs, then Criteria #2 is also rendered meaningless.

Criteria #2, the Section titled “Expansion of Existing Emergency Department Facility,” further provides that:

Applicants seeking expansion of the existing host hospital ED through the establishment of a FSED in order to decompress patient volumes should demonstrate the existing ED of the host hospital is operating at capacity. **This determination should be based upon the annual visits per treatment room at the host hospital’s emergency department (ED)** as identified by the American College of Emergency Physicians (ACEP) in Emergency Department Design: A Practical Guide to Planning for the Future, Second Edition as capacity for EDs.

Standards and Criteria, p. 6 (emphasis added). TriStar Hendersonville’s visits per treatment room for calendar years 2020, 2021, and 2022 – as found by the Staff – met the ACEP capacity guidelines.

e. Sumner County is facing Capacity Challenges at local EDs

Even if the “All EDs” provision in Criteria #1 is about something other than orderly development and could be construed to be in harmony with other parts of Criteria #1 that focus on the host hospital’s capacity issues, Sumner County *is facing ED capacity challenges*. The countywide data for Sumner County shows capacity challenges for Emergency Room access in the County and that those challenges continued after the pandemic into 2022.

Just recently (after the TriStar Hendersonville CON Application was deemed complete), the Tennessee Hospital Association (THA) data for all hospitals became available. The chart below includes the 2022 THA data, which was not available previously. As can be seen from this data, as a community, the emergency room visits per room in Sumner County exceeded the ACEP standards for all four years, 2019, 2020, 2021, and 2022. Further, the ER visits as a whole in the County were higher in 2022 than the pre-pandemic year of 2019.

Sumner County Facility ED Visits per Treatment Room				
Year	ED Visits	ER Treatment Rooms	ED Visits per ER Treatment Room	ACEP Mid Range Guideline
CY 2019	89,101	62	1,437	1,080 to 1,386 (range based on ED volume)
CY 2020	77,479	62	1,250	
CY 2021	86,261	62	1,391	
CY 2022	90,075	62	1,453	
Note: JARS for CY 2019 through 2021; THA Data for CY 2022				
TriStar Hendersonville is Mid-Range per ACEP Guidelines, Table 2A1, page 1N 28				

In addition, TriStar Hendersonville’s internal data for January 1 through June 30, 2023, shows TriStar Hendersonville’s ED visits on track for 39,435 annualized visits in 2023, which is more than 2019 and an increase over 2022. This equates to 1,972 visits per ED treatment room, **exceeding ACEP guidelines by 40%**.

TriStar Hendersonville Medical Center				
Visits per Treatment Room, CY 2019 through 2023 YTD Annualized				
Timeframe	Total Visits	# of Rooms	# Visits per Room	ACEP Mid Range
CY 2019	35,578	20	1,779	1,386
CY 2020	29,860	20	1,493	1,315
CY 2021	35,519	20	1,776	1,386

CY 2022	37,945	20	1,897	1,386
YTD 2023A	39,435	20	1,972	1,406

2. Wait Time Performance

The Staff also found that TriStar Hendersonville did not meet a portion of Criteria #1 **because its (and SRMC's) wait times are too good.**⁵ As the HFC knows from prior projects, all Tennessee HCA hospital EDs have excellent wait time performance due to a company-wide emphasis on making sure patients are seen promptly.

While wait times may be a legitimate measure of capacity challenges, the **Criteria #1 does not require an applicant to have bad wait times** to qualify for a CON. In fact, Criteria #1 specifically provides that: "Host hospitals applying to establish a FSED displaying efficiencies in care delivery via high volumes and low wait time **should not be penalized** in the review of this standard." Criteria #1, pp. 5-6 (emphasis added).

We have reviewed all FSED applications since the 2021 CON Reform law went into effect, and **no post-CON Reform law application was found to not meet Criteria #1 because the applicant had good wait times** (wait times lower than the state average).

Notably, the Criteria themselves are internally inconsistent with regard to Wait Time performance. In Criteria #4 good (i.e. low) wait times are required to show quality ("OP-18 Median Time from ED Arrival to Departure for Discharged ED Patients"), which is the very same wait time metric used in Criteria #1.⁶

As you know, the only measurable quality standard among the list in Criteria #4 is wait time performance: OP-18 -- Median Time from ED Arrival to Departure for Discharged ED Patients. **The Staff Report does not mention that TriStar**

⁵ "Each of the two hospital facilities in Sumner County reported ED Time Scores below the Tennessee Average for their respective facility types. Therefore, the applicant does not appear to meet this portion of the Criterion as it relates to OP-18 Median Time from ED Arrival to ED Departure for Discharged ED Patients." Staff Report, p. 5.

⁶ Criteria #4 provides in pertinent part:

4. Host Hospital Emergency Department Quality of Care: Additionally, the applicant shall provide data to demonstrate the quality of care being provided at the ED of the host hospital. The quality metrics of the host hospital should be in the top quartile of the state in order to be approved for the establishment of a FSED. The applicant shall utilize the Joint Commission's hospital outpatient core measure set . . . and are available through the CMS Hospital Compare website. . . . **OP-18 Median Time from ED Arrival to Departure for Discharged ED Patients.**

Standards & Criteria, p. 8 (emphasis added).

Hendersonville is in the top quartile of the state in wait time performance and thus meets Criteria #4.

3. Left Without Being Seen ("LWBS")

At HCA hospitals, good wait times go hand in hand with good LWBS statistics. The same rationale for not penalizing hospitals that perform well in wait times should apply to LWBS statistics.

As the Staff noted, SRMC's LWBS data is above average for Tennessee hospitals.⁷ This is some evidence of ER capacity challenges in Sumner County. The Staff specifically mentioned "the apparent high rate of patients who left the [SRMC] emergency department without being seen as of the last reporting period (CY2021)." Staff Report at p 6.

TriStar Hendersonville's good LWBS performance should not penalize its ability to improve patient access by bringing needed emergency care to the patients who choose to go to a TriStar Hendersonville ER facility.

B. Criteria #3

Criteria #3 provides that:

Relationship to Existing Similar Services in the Area: The proposal shall discuss what similar services are available in the service area and the trends in occupancy and utilization of those services. **This discussion shall include the likely impact of the proposed FSED on existing EDs in the service area** and shall include how the applicant's services may differ from existing services. Approval of the proposed FSED should be contingent upon the applicant's demonstration that existing services in the applicant's proposed geographical service area are not adequate and/or there are special circumstances that require additional services.

Standards & Criteria, p. 7 (emphasis added).

As noted before, the 2021 CON Reform law removed "orderly development" and impact on existing providers from the legal foundation for the Criteria. Therefore, the provision in Criteria #3 that calls for the evaluation of "the likely impact of the proposed FSED on existing EDs in the service area" is not legally sound.

In evaluating Criteria #3, the Staff concluded:

⁷ "The percentage of patients who left the emergency department before being seen was below both the state (3%) and national (3%) average for the host hospital, TriStar Hendersonville Medical Center at (1%), while [SRMC] reported a (5%) rate which exceeded the state and national averages. Therefore, this portion of the Criterion appears to be partially met based on the apparent high rate of patients who left the [SRMC] emergency department without being seen as of the last reporting period (CY2021)." Staff Report, p. 6.

Given the fact that there are currently two existing emergency departments located within the proposed ZIP Code of the project site (37066 – Gallatin), it does not appear that the existing emergency services “are not adequate and/or there are special circumstances that require additional services”, beyond the data demonstrating a high rate of patients who left the emergency department without being seen at Sumner Regional Medical Center.

However, the applicant has demonstrated significant growth in utilization of its host hospital by residents of ZIP Code (37066 – Gallatin) as well as a need to decompress its own emergency department and accommodate future population growth in the service area.

* * *

It appears that this criterion has been partially met.

Staff Report, p. 8.

TriStar Hendersonville acknowledges that the Staff found the significant growth in the service area to be a valid “special circumstance,” but disagrees with the Staff’s conclusion that Criteria 3 was only partially met. Staff Report, p. 8. Criteria #3 continues to use an orderly development approach removed from the CON law in 2021, and special circumstances fully demonstrate the consumer advantage provided by the proposed FSED.

1. Criteria #3 is rooted in improper Orderly Development Analysis

Criteria 3 states, in part: “This discussion shall include the likely impact of the proposed FSED on existing EDs in the service area” Standards & Criteria, p. 7. (emphasis added). The consideration of impact on existing providers was removed from CON law in 2021. As noted, orderly development was formerly used to determine “whether the proposed project will have negative effects or impact on other existing providers. *In re TriStar Southern Hills Medical Center Emergency Department at I-65*, No. 25.00-130740J, at 44 (Initial Order, May 31, 2017) (emphasis added). In 2021, the legislature removed orderly development from the statute.

2. Special Considerations

The Staff did not discuss how TriStar Hendersonville’s services differ from SRMC’s or the quality differences between the facilities. Further, TriStar Hendersonville’s ER is being chosen by many Gallatin residents, despite the fact that there are two SRMC ERs in the community, and some Hendersonville residents live closer to the proposed FSED location and will be better served by that location. These “special considerations” show the need for TriStar Hendersonville’s Gallatin FSED.

a. TriStar Hendersonville's Services

TriStar Hendersonville provides a number of services in its ED, which are unavailable at SRMC. These include, but are not limited to, round-the-clock on-call GI coverage in the ED and on-call Neonatal and Maternal Fetal coverage. Moreover, TriStar Hendersonville's main campus possesses a Level II NICU and vascular services, which SRMC does not possess.

b. Quality Considerations

Stark differences exist between the quality of care offered at SRMC and TriStar Hendersonville. With regard to quality of care, TriStar Hendersonville possesses a **4 Star rating from CMS** and currently has an **"A" Leapfrog Score**. Conversely, SRMC possesses a 2 Star rating from CMS and currently has a **"C" Leapfrog Score**. Below is a table that containing excerpts of the measures used in calculating the Leapfrog Score for Spring 2023, comparing TriStar Hendersonville with SRMC. TriStar Hendersonville repeatedly ranks higher in quality than SRMC.

Measure	TriStar Hendersonville Score	SRMC Score	Worst Performing Hospital	Avg. Performing Hospital	Data Source	Time Period Covered
Patient falls and injuries	0	0.944	2.229	0.437	CMS	7/1/2019-12/31/2019 & 7/1/2020-6/30/2021
Infection in the blood	0	1.052	4.462	1.077	2022 Leapfrog Survey	7/01/2021-6/30/2022
Infection in the urinary tract	0	0.268	3.516	0.862	2022 Leapfrog Survey	7/1/2021-06/30/2022
MRSA Infection	0.758	3.448	3.918	1.095	2022 Leapfrog Survey	7/01/2021-6/30/2022
C. diff. Infection	0.06	0.691	2.066	0.489	2022 Leapfrog Survey	07/01/2021 - 06/30/2022
Harmful Events	0.87	1.15	2.7	0.98	CMS	7/1/2019-12/31/2019 & 7/1/2020-6/30/2021

c. Gallatin (37066) Residents

Moreover, letters of support from Gallatin residents help explain the preference for TriStar Hendersonville among some Gallatin residents, sometime due to patients' perceptions of the quality at SRMC. For example, Brenda Maday notes,

In the past, my family and I have been forced to go to Sumner Regional. In these circumstances, TriStar was preferred but Sumner Regional was closer, so we went there. As the Gallatin population continues to grow, I expect that my family along with the many members of my community who prefer TriStar Health will be forced to make this compromise. I am worried that this trend, if it continues, will lead to Sumner Regional becoming

overwhelmed and placing the health of the community at risk. The addition of this new TriStar ER incentiv[iz]es both providers to ensure they provide the best possible care and provides the community with options in care.

Similarly, Gallatin resident Gabrielle Pittman discusses her preference for TriStar Hendersonville, despite other emergency rooms being closer:

I personally have driven family members and myself from further locations to Hendersonville's emergency department due to my excellent experiences there. It would be a wonderful service to have available closer to home. . . . Gallatin has one stand-alone ER that is much closer to Hendersonville and very often has longer than necessary wait times. If given the option, I, and many that I know in my community will choose TriStar Hendersonville every time for emergency care.

Michael Hitzelberger discusses his personal experience with both EDs in his Letter of Support:

I went to the Gallatin Sumner Regional ER within the last year, for a kidney stone. It was the first one I ever had. I wasn't sure what it was, nor did the nurse station register station of the ER know. I sat there in severe pain for hours at night and they had terrible service. The people at the front desk kept talking as if I would get in, so I waited but I never did. After several hours of severe pain, when I was exhausted way past midnight, I drove to the TriStar Hendersonville ER and received GREAT service.

d. Hendersonville (37075) Residents

TriStar Hendersonville's patients in 37075 (Hendersonville) see the need for the Gallatin FSED. The Staff needs to know that Letters of Support in favor of the FSED show that Hendersonville residents will also use the Gallatin FSED. For example, Kelly Estepp, a Hendersonville resident, notes her close proximity to the FSED location and her support for the facility: "I am a resident of Hendersonville who lives within close proximity to the proposed location for the new emergency room... I support the care provided by TriStar Health and would therefore, during an emergency, most likely use their services"

Brian Gill, also a Hendersonville resident, states:

Anyone can appreciate the need for an ER should they need one and here in the Gallatin/Hendersonville area, we desperately need more healthcare options. My family and I generally prefer TriStar Health as a provider because in our experience, they are professional, respectful, and supportive. TriStar Health is also wonderful for quick service even at times when they

are experiencing overwhelming demand. I would therefore like to have easy access to a TriStar Health FSER in case of an emergency.

That some Hendersonville residents will live closer to the proposed FSED is highlighted in the Letter of Support from Jaime Clary, Mayor of Hendersonville:

The proposed Gallatin ER will relieve Hendersonville's ER of capacity constraints. It will not only provide a high-quality ER option for Gallatin residents who choose to travel to Hendersonville for their ER services, but also for Hendersonville residents that live close to the Gallatin location. . . . This location will be helpful to me, the residents of Hendersonville, and the residents of the part of Sumner County that is growing the fastest.

e. Growth

The Staff found the projected growth of the service area to be a special consideration warranting the additional FSED. TriStar Hendersonville submits that this special consideration alone should be enough to demonstrate the Consumer Advantage provided by the proposed facility. Overall, the proposed service area is expected to experience 7.8% growth, with 37066 (Gallatin) experiencing the largest growth at 9.6%. By age range, the largest growth in all Zip Codes is expected to occur in the Age 65+ category. Staff Report, TriStar Hendersonville, CN2305-012, p. 10.

Service Area Population by Age Group (2023-2028)

Zip Code	Age 0-17	Age 18-44	Age 45-64	Age 65+	Total
2023					
37048 (Cottontown)	1,572	2,251	2,028	1,340	7,191
37066 (Gallatin)	14,037	21,112	16,311	11,880	63,340
37075 (Hendersonville)	16,583	24,455	19,742	13,203	73,983
Total Service Area	32,192	47,818	38,081	26,423	144,514
2028					
37048 (Cottontown)	1,598	2,373	2,014	1,625	7,610
37066 (Gallatin)	14,750	22,611	17,372	14,674	69,407
37075 (Hendersonville)	16,880	25,839	20,150	15,971	78,840
Total Service Area	33,228	50,823	39,536	32,270	155,857
Percent Growth					
37048 (Cottontown)	1.7%	5.4%	-0.7%	21.3%	5.8%
37066 (Gallatin)	5.1%	7.1%	6.5%	23.5%	9.6%
37075 (Hendersonville)	1.8%	5.7%	2.1%	21.0%	6.6%
Total Service Area	3.2%	6.3%	3.8%	22.1%	7.8%

Source: CN2305-012, Original Application, Page 17

The projected population growth in 37066 (Gallatin) could easily exceed the approximate 6,000 person projected increase because Gallatin has more than 90 projects underway, ranging from preliminary approvals to those under construction. More than 50 of these include a variety of residential developments from single family to townhomes to multi-family buildings. Of the residential projects, there are 27 under construction

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which include more than 7,900 dwelling units/homes and 16 additional residential projects with approximately 1,700 units/homes which received approval.

In addition, the non-residential projects include several hotels, another assisted living facility, multi-tenant retail and office developments, an event center, mixed use projects, and many other commercial developments. Moreover, the proposed location of the Gallatin FSED is central to many of these developments.

In sum, the inappropriate consideration of orderly development, and the proper consideration of the special circumstances of enhanced services, superior quality/patient preference, and substantial growth show that TriStar Hendersonville meets Criteria #3.

III. Conclusion

TriStar Hendersonville submits that the provisions in Criteria #1 and Criteria #3 that focus on impact on existing providers are no longer warranted due to the change in the CON law in 2021 and in any event has been given too much weight by the HFC Staff.

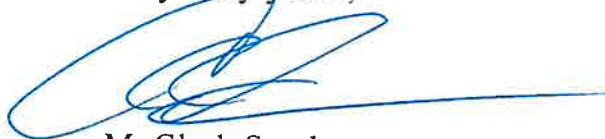
TriStar Hendersonville submits that the Criteria create an impossible situation if the Staff's reading of Criteria #1 goes forward because as interpreted by the Staff, Criteria #1 requires bad wait time performance while Criteria #4 requires good wait time performance. Notably, the Staff's finding that good wait time performance causes Criteria #1 to not be met is inconsistent with any other FSED CON Application evaluated under the 2021 CON law on this point.

Finally, TriStar Hendersonville submits that Criteria #3 improperly includes "orderly development" considerations and that the Staff's analysis should recognize that special considerations warrant a new FSED in Gallatin.

Accordingly, TriStar Hendersonville requests that the Staff issue a revised Staff Report finding that the TriStar Hendersonville CON Application CN2305-012 meets the legally relevant portions of the Department of Health's Standards & Criteria.

If you have any questions or need additional information, please do not hesitate to contact me or my associate who is working on this case with me, Hilary Dennen (hdennen@gsrm.com).

Very truly yours,



M. Clark Spoden

cc: Phillip M. Earhart (Phillip.M.Earhart@tn.gov)